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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,330	10/22/2003	Istvan Boldogh	265.00390101	1384

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,330	BOLDOGH ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,12-15,27,28 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,12-15,27,28 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/04;3/7/08;8/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-6, 8, 12-15, 27, 28 and 33-38 are pending.

Applicants' amendment filed August 29, 2008 is acknowledged. Applicants' response has been fully considered. Claims 1, 6, 12, 27 and 28 have been amended. Therefore, claims 1-6, 8, 12-15, 27, 28 and 33-38 are examined.

Restriction Requirement

2. Applicants have requested to rejoin and examine all SEQ ID NOs:1-34 in the claimed methods. Upon reconsideration, all SEQ ID NOs:1-34 are included for examination.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 27, 28 and 33-38 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 9 in the amendment filed August 29, 2008.

Withdrawn Claim Rejections -- 35 USC § 102

4. The previous rejection of claims 27 and 33-35 under 35 U.S.C. 102(b) as being anticipated by Leszek *et al*. (Archivum Immunologiae et Therapiae Experimentalis 47, 277-385 (1999), is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 9-10 in the amendment filed August 29, 2008.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 27 and 33-35 are rejected under 35 USC 103 (a) as being obvious over Leszek *et al.* (Archivum Immunologiae et Therapiae Experimentalis 47, 277-385 (1999).

Leszek *et al.* teach the plaques in the Alzheimer's disease (AD) patients represent β-amyloid deposits, which play a key role in the pathogenesis of AD (page 378, left column); and the use of colostrinin (100 μg per tablet, every second day) in the treatment of Alzheimer's disease (AD) patients, eight of 15 AD patients treated with colostrinin improved, and in 7 others the disease had stabilized (pages 380-382; Tables 2-3; Fig. 2). Although Leszek *et al.* do not specifically disclose β-amyloid induces apoptosis in a cell, the reference does indicate that β-amyloid deposits play a key role in the pathogenesis of AD, and the use of an effective amount of colostrinin in the treatment of AD. Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the use of an effective amount of colostrinin for treatment of AD as suggested by Leszek *et al.* would include determining an effective amount of colostrinin and reducing the toxic effect of β-amyloid (e.g., β-amyloid induced apoptosis; claims 27 and 33-35), which results the claimed invention.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-6, 8, 12-15, 27-28 and 33-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 and 19-22 of co-pending application 11/509,979 (based on the amendment filed September 3, 2008). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8, 12-15, 27-28 and 33-38 in the instant application disclose a method for inhibiting apoptosis, a method for protecting against DNA damage, or a method of reducing β-amyloid or retinoic acid induced apoptosis in a cell, the method comprising determining an effective amount of an apoptosis inhibitor or a compound in the cells, and contacting the cell with the effective amount of an apoptosis inhibitor or a compound selected from the group consisting of colostrinin and a constituent peptide of colostrinin (i.e., SEQ ID NO:1-34). This is obvious variation in view of claims 10-13 and 19-22 of the copending application which disclose a method for inhibiting apoptosis, a method for protecting against DNA damage, or a method of reducing β-amyloid or retinoic acid induced apoptosis in a cell, the method comprising contacting the cell with an effective amount of an apoptosis inhibitor or a compound, wherein the apoptosis inhibitor or the compound is colostrinin or a constituent peptide of colostrinin (SEQ ID NO:1-34). Both sets of claims are directed to a method for inhibiting apoptosis, a method for protecting against DNA damage in a cell, or a method of

reducing β-amyloid or retinoic acid induced apoptosis in a cell, by contacting the cell with an effective amount of colostrinin or a constituent peptide of colostrinin (e.g., SEQ ID NO:1-34). Therefore, claims 1-6, 8, 12-15, 27-28 and 33-38 in instant application and claims 10-13 and 19-22 of the copending application are obvious variations of a method for inhibiting apoptosis, a method for protecting against DNA damage in a cell, or a method of reducing β-amyloid or retinoic acid induced apoptosis in a cell, by contacting the cell with an effective amount of colostrinin or a constituent peptide of colostrinin (e.g., SEQ ID NO:1-34).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants request that the rejection be held in abeyance until the identification of allowable subject matter. At that time a terminal disclaimer will be submitted (page 8 of the response).

Applicants' response has been considered, and the rejection is maintained until a terminal disclaimer is filed.

Conclusions

7. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
November 29, 2008